# QUESTIONS & ANSWERS:
# NIH PUBLIC ACCESS POLICY

## A. Specifics and scope of the final policy



## B. Background and rationale for the policy

## 1. What is the NIH Public Access Policy?

The Public Access Policy requests NIH-funded investigators to submit to the NIH National Library of Medicine's PubMed Central an electronic version of the author's final manuscript upon acceptance for publication, resulting from research supported in whole or in part, with direct costs[1] from NIH. The Policy provides the public, who have invested substantially in NIH-supported research, with better access to research publications resulting from NIH-funded research. This is accomplished by establishing a comprehensive, searchable electronic archive of NIH-funded research publications, providing publicly available access to all.

## 2. Is the NIH Public Access Policy a requirement?

No. It is a request to NIH funding recipients that will enable them also to fulfill the existing requirement to provide publications as part of progress reports.

## 3. What are NIH's Public Access operating costs likely to be?

By building on an existing information technology infrastructure housed at the NLM, the NIH Public Access Policy can be an exceptionally cost-effective means to accomplish its goals of archiving, facilitating program management, and enhancing accessibility. Estimates of $2-$4 million per year reflect incremental costs to create and then maintain a website for submitting authors' final manuscripts and for Extensible Markup Language (XML) tagging of the manuscripts into PubMed Central's archival format.

## 4. What is the anticipated timeframe for providing the public with access to publications that have been submitted to the NIH by its investigators?

After listening to the views of publishers, patient advocates, and scientists, the NIH Public Access Policy requests and strongly encourages that posting for public accessibility through PubMed Central occur as soon as possible. NIH realizes that in certain circumstances, immediate posting may not be possible. In such cases, the Policy allows authors to consider the range for specifying posting within twelve months of the publisher's official date of final publication. NIH expects that only in limited cases will authors deem it necessary to select the longest delay period.

## 5. Does the NIH Public Access Policy apply to book chapters or editorials?

No. The Policy does not apply to book chapters, editorials, reviews, or conference proceedings.

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[1] Costs that can be specifically identified with a particular project or activity. NIH Grants Policy Statement, Rev. 12/2003; http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part2.htm#_Toc54600040

## 6. Will NIH provide to the public translated versions of scientific papers so that the information is readily understandable to a lay person?

While public access to this electronic archive has the potential to help the lay public see the breadth of the research that NIH funds, each NIH Institute and Center also has an active staff that assist the public in understanding the results of NIH-funded research. This staff, often with the assistance of third parties and patient advocacy groups, works diligently to develop, review, and disseminate high-quality educational and informational materials on various health and research topics. Many of these products highlight the publications of NIH-funded researchers. For example, the National Library of Medicine's consumer health site, Medline Plus (http://www.nlm.nih.gov/medlineplus/), houses extensive information on more than 650 health conditions. NIH believes that these information products are an effective tool to advance NIH's strong commitment to improving public health through research.

## 7. Is the NIH Public Access Policy related to the public registration of clinical trials?

The Policy does not influence whether or not a clinical trial is posted on clinicaltrials.gov. However, if it is an NIH-funded trial to test the effectiveness of a drug to treat a serious or life-threatening disease or condition, it would likely be posted to clinicaltrials.gov, and a link would be provided to the full text of the article for the benefit of the public.

## 8. Will the NIH Public Access Policy apply to NIH-supported investigators in foreign countries?

Yes. The Policy applies to all NIH-funded investigators, including those in foreign countries. The PubMed Central (PMC) archive will be available through the Internet, so all investigators will have access to it, provided they have a computer with an Internet connection. NIH appreciates that the scientific community is truly global and interchange among scientists worldwide is essential for professional and scientific advancement. The Policy does not require that PMC, NIH's digital archive for biomedical, clinical and behavioral research, be the sole repository for NIH-funded research publications. Others may also choose to post and/or archive peer-reviewed publications resulting from NIH-funded research, subject to permission from any copyright holders.

## 9. How does the NIH Public Access Policy differ from the data sharing requirement?

The NIH Public Access Policy and the NIH data sharing policy are separate and distinct policies.

The NIH data sharing policy requires investigators that submit an NIH grant application seeking $500,000 or more in direct cost support in any single year to include a plan for data sharing or state why data sharing is not possible. Detailed information regarding this policy, including frequently asked questions, can be found at the following NIH website: http://grants2.nih.gov/grants/policy/data_sharing/.

By comparison, the NIH Public Access Policy is voluntary and applies to peer-reviewed final manuscripts accepted for publication that have resulted from NIH-funded research. The Public Access Policy applies to final manuscripts - not specifically to research data.

## 10. Why should there be a public resource of published peer-reviewed research findings of NIH-funded research?

The NIH Public Access Policy is intended to meet several important goals:

- Creating a stable archive of peer-reviewed research publications resulting from NIH-funded research to ensure the permanent preservation of these vital published research findings;

- Securing a searchable compendium of these peer-reviewed research publications that the NIH and its awardees can use to manage more efficiently and to understand better their research portfolios, monitor scientific productivity, and ultimately, help set research priorities; and

- Making published results of NIH-funded research more readily accessible to the public, health care providers, educators, and scientists.

## 11. What was wrong with the previous system?

The previous system did not provide NIH with the stable archive of publications that it needs to manage more efficiently its research portfolio and ensure the permanent preservation of these vital published findings. Nor did it provide the public with the ready access to these records that the Public Access Policy is intended to give.

Before the Public Access Policy, individuals who were not affiliated with an academic, medical library or research hospital generally gained access to the peer-reviewed publications of NIH-funded investigators by visiting a medical library or by paying for a subscription to journals themselves. NIH's Public Access Policy allows individuals to access the peer-reviewed and published scientific works of NIH-funded investigators through the Internet and without a fee.

## 12. What is PubMed Central and who is able to access it?

PubMed Central (PMC) is the NIH digital repository of full-text, peer-reviewed biomedical, behavioral, and clinical research journals. It is a publicly-accessible, stable, permanent, and searchable electronic archive. Anyone with entry to the Internet can access PMC (http://www.pubmedcentral.gov/).

## 13. Is a government-run repository the best approach?

Yes. NIH believes that a central archive, operated by NIH, is the best approach to assist it in managing more efficiently its research portfolio. PubMed Central (PMC) is the NIH National Library of Medicine's (NLM) digital repository of full-text, peer-reviewed biomedical, behavioral, and clinical research journals. NLM and its predecessor organizations have been archiving the biomedical literature for over 150 years and is

experienced in maintaining a stable archive of scientific information that is currently used by over one million users every month. Relying on the existing PMC infrastructure is a cost-effective means to achieve the agency's goals. In addition, NIH's policy does not state that PMC will be the sole repository for these manuscripts and publications. Others may also post and/or archive them, subject to permission from any copyright holders. Preservation of the biomedical literature is a responsibility that is specifically mandated in NLM's authorizing legislation, found at 42 U.S.C. 286(b)(1) and one that has successfully been carried out by the NLM since 1836. It is logical in this electronic era to expect libraries, and particularly national libraries, to continue this vital function, including keeping pace with the ever-changing technology surrounding document preservation. Updating the data formats to keep up with the changes in technology and the needs of biomedical research requires an ongoing investment in research and development, which is within the NIH mission. As the electronic article increasingly becomes the authoritative and most useful document for researchers, and as scientists are actually computing on the contents of these documents - the text itself as well as the associated data - the impermanence of the publishers' websites presents a substantial risk. Creating such an archive is a historical and necessary NIH responsibility.

### 14. Rather than archive manuscripts in NIH's PubMed Central, why not provide links to an entity such as "HighWire" which contains 650 journals? What about simply linking to another website?

One of the primary goals of PMC is the creation of a permanent, digital archive of journal literature, which by definition, means the full text must be deposited in PMC rather than relying on outside databases whose permanence can not be guaranteed. This searchable archive will enable NIH program officials to manage their research portfolios more efficiently, monitor scientific productivity, and ultimately, help set research priorities. This strategy also will enable NIH to advance its goal of creating an end-to-end, paperless grants management process. Finally, it will make the publications of NIH-funded research more accessible to and searchable for the public, health care providers, educators, and scientists.

While links exist to journal articles that are publicly accessible, these are not sufficient. The Policy addresses this deficiency in that all articles in PMC, regardless of their original format, are converted into a single, explicit, and well-specified data format. This format is known as the NLM Journal Article Extensible Markup Language (XML) Document Type Definition (DTD). Further, as new needs arise, and as technology and applications change, there is a single, uniform base upon which to build.

It is worth clarifying that NIH does not require or expect that PMC be the sole repository for NIH-funded research publications. Others may choose to post and/or archive peer-reviewed publications resulting from NIH-funded research, subject to applicable laws or permission from any copyright holders.

### 15. How many publications are associated with NIH-supported research each year?

It is estimated that the results of NIH-supported research were described in 60,000 – 65,000 published papers in 2003. NIH developed this estimate by searching the PubMed database

for citations with 2003 publication dates that include a reference to a specific NIH grant number.[2]

## 16. What role does NIH have in the current publishing process?

The NIH supports the current publishing process by providing its funded investigators with an estimated $30 million annually in direct costs for publication expenses, including page and color charges and reprints. In addition, NIH provides funds, through indirect costs, to research institutions that use these funds for library journal subscriptions and electronic site licenses. NIH also supports the current process by encouraging publication of NIH-supported original research in scientific journals.

## 17. How much does it cost to publish a scientific article?

Publication costs have been reported to range from a few hundred dollars per article to several thousand dollars per article. For example, see the analysis in two reports commissioned by the Wellcome Trust, "An Economic Analysis of Scientific Research Publishing" (http://www.wellcome.ac.uk/doc_WTD003181.html) and "Costs and Business Models in Scientific Research Publishing" (http://www.wellcome.ac.uk/doc%5Fwtd003185.html).

## 18. What are the current time-to-access policies for science, medical, and technical journals?

There is a wide range of time-to-access policies within the publishing world. Some of the variables that affect time-to-access include differences among scientific fields (e.g., clinical versus basic research) and variability in business models determined by a range of issues including number of article submissions, acceptance rate, subscription base, and many other factors.

## 19. What steps did NIH take in order to solicit opinions from its stakeholders regarding this issue and did they have an opportunity to comment on the Public Access Policy before it was made final?

The NIH Director, Elias A. Zerhouni, M.D., held a series of discussion meetings to hear and consider the opinions and concerns of publishers, scientists, patient advocates, and representatives of scientific associations and other organizations. The meetings were designed to ensure that discussions of stakeholder issues could occur. The NIH extended invitations to a broad base of participants to ensure balanced representation of opinions. In many cases, participants represented more than one stakeholder group, such as scientists who were also editors and reviewers of scientific journals. After carefully considering the views of publishers, patient advocates, scientists, university administrators, and others, the NIH published its proposed NIH Public Access Policy in the **NIH Guide for Grants and Contracts** on September 3, 2004, http://grants1.nih.gov/grants/guide/notice-files/NOT-

[2] These figures are derived from searching the PubMed database for citations with 2003 publication dates that include a reference to a specific NIH grant number. The data provide useful estimates of articles funded by NIH, although individual journal counts may vary slightly if calculations are performed using other sources or search strategies.

OD-04-064.html and in the **Federal Register** on September 17, 2004, http://a257.g.akamaitech.net/7/257/2422/06jun20041800/edocket.access.gpo.gov/2004/04-21097.htm for public comment. During the comment period, the NIH received over 6,000 comments via web, fax, mail, and e-mail. The final Policy reflects consideration of public comments received on the proposed policy through November 16, 2004, i.e., 60 days from the date of publication of the proposed policy in the **Federal Register.**

## 20. Are other funding organizations considering this issue?

Yes. Many other organizations and countries are considering the public access issue including France, Japan, Germany, the United Kingdom, Australia, and Canada. The Howard Hughes Medical Institute and the Wellcome Trust are on the record encouraging and supporting public access to the results of research conducted by their scientists.

## 21. Aren't scientific abstracts, which are currently freely available, sufficient? Why does the public need full text articles?

The public encompasses a wide array of individuals, ranging from the lay public and educators to health care providers. Many of these individuals require more information than is provided in an article summary and must gain access to the complete article. In addition, the goal is to establish and maintain a centralized, permanent archive of all scientific publications arising from NIH-funded research.

## 22. Will the NIH Public Access Policy improve research for medical cures?

NIH believes that improved access through PubMed Central (PMC) to peer-reviewed, final manuscripts of NIH-supported investigators will likely facilitate scientific progress because it will enable NIH to manage more efficiently and understand better its research portfolio and ultimately, help set research priorities. The NIH encourages the sharing of ideas, data, and research findings to help accomplish its important public mission to uncover new knowledge that will lead to better health for everyone. As such, NIH envisions that the PMC resource will have widespread and varied use to the research community. It will create a stable, permanent, and searchable archive of peer-reviewed research publications that NIH and the public can use, without a fee, to review scientific productivity, monitor the state-of-the-science, and apply such knowledge to accelerate medical research. Greater integration between the multiple and large research data bases now available to researchers, such as Genbank and PubChem, to an archive of NIH-funded publications has the potential to enhance research in novel ways.

## 23. Is the NIH mandating changes to science, medical, and technical publishing?

No. NIH is not proposing changes for publishing. The NIH has considered the wide range of issues related to public access to publications, and this Policy is designed to preserve the critical role of journals and publishers in peer review, editing, and scientific quality control processes. It is not intended to alter the manuscript submission process, investigator choice of journal for publication, or existing publication processes in any way. The NIH has established and intends to maintain its dialogue with publishers, investigators, representatives from scientific associations, and the public to help ensure that the quality and success of the current peer review system is preserved.

## 24. Will NIH's Public Access Policy harm scientific publishing?

At this time, NIH is not aware that there will be a substantial impact. For example, only a portion of articles published in scientific journals result from research funded by the NIH. As such, it is unlikely that scientists and libraries would use the NIH Public Access Policy as the rationale for replacing their journal subscriptions. If they did, they would be able to access only a fraction of a journal's content. With regard to subscriptions, it is also important to note that there are many other components of journals, such as science news, industry information, literature reviews, job announcements, functional websites, and other time-sensitive products that bring value to the reader; these are not a part of the PubMed Central archive.

An increasing number of journals already provide access to the published article immediately or within one year of the publication. Most of the highly cited journals provide some form of public access within this timeframe.

In addition, the NIH Public Access Policy does not affect authors' freedom to choose the vehicle or venue for publishing their results. NIH expects that its awardees will continue to publish the results of their research consistent with their professional autonomy and judgment, in order to advance science as efficiently and comprehensively as possible.

## 25. Can authors and journals continue to assert copyright in scientific publications resulting from NIH funding?

Yes. The Public Access Policy does not affect the ability to assert copyright. Funding recipients may continue to assert copyright in works arising from NIH-funded research, and they may assign these copyrights to journals as is the current practice. Copyright holders may enforce these copyrights as before. A member of the public viewing or downloading a copyrighted document from PubMed Central (PMC) is subject to the same rights and restrictions as when copying an article from the library. For example, making a copy of an article for personal use is generally considered to be a "fair use" under copyright law. For uses that fall outside of the fair use principle, permission to reproduce copyrighted materials must be obtained directly from the copyright holders. PMC currently includes a copyright notice alerting the public to the rights of copyright holders and will continue to post this notice as it has done in the past.

## 26. Can NIH provide language that could be used in a copyright agreement between an author or institution and a publisher?

The Policy encourages authors to exercise their right to give NIH a copy of their final manuscript. While individual copyright arrangements can take many forms, NIH encourages investigators to sign agreements that specifically allow the manuscript to be deposited with NIH for public posting on PubMed Central as soon as possible after journal publication. Institutions and investigators may wish to develop particular contract terms in consultation with their own legal counsel, as appropriate. But, as an example, the kind of language that an author or institution might add to a copyright agreement includes the following:

"Journal acknowledges that Author retains the right to provide a copy of the final manuscript to NIH upon acceptance for Journal publication or thereafter, for public archiving in PubMed Central as soon as possible after publication by Journal."

## 27. How is the potential impact on publishers being considered?

Through open meetings with publishers and a public comment period on the proposed Public Access Policy, the NIH has established, and will continue, a dialogue with publishers to help ensure that their opinions and concerns are heard. The NIH recognizes that the rising global role and importance of the Internet has caused many industries, including publishers of peer-reviewed scientific articles, to shift business practices to accommodate a changing world. Currently, a variety of business models exist within the publishing industry — some of which already involve immediate or delayed electronic access to published scientific works. However, issuance of this Policy is the beginning of a process that will include refinement as experience develops, outcomes are evaluated, and public dialogue among all the stakeholders is continued.

A NIH Public Access Advisory Working Group of the NLM Board of Regents[3] will be established. The Working Group will be composed of stakeholders that will advise NIH/NLM on implementation and assess progress in meeting the goals of the NIH Public Access Policy. Once the system is operational, modifications and enhancements will be made as needed with the Working Group, or a permanent subcommittee of the Board, providing ongoing advice on improvements.

## 28. Will this policy be an added burden to NIH-supported investigators and research institutions?

Public Access submissions will provide NIH-supported investigators with an alternate means by which they can fulfill the existing requirement to provide publications as part of progress reports and other application and close-out procedures. It is anticipated that in the future investigators applying for new and competing renewal support from the NIH will also utilize this resource by providing links in their applications to their PubMed Central-archived information. NIH anticipates that this may reduce, rather than increase, burden for investigators who choose to use this method as part of their application/progress report/close-out submissions.

## 29. Will the NIH Public Access Policy harm the quality of peer review?

No. NIH does not anticipate that its policy will harm or otherwise affect the peer review process for scientific papers. The Policy requests that NIH-funded investigators submit their final manuscripts upon acceptance in a peer-reviewed journal. NIH highly values traditional routes of research information dissemination through publication in scientific, peer-reviewed journals. Peer review is a hallmark of quality for journals and is vital for

[3] Established pursuant to 42 U.S.C. 286a, section 466 of the Public Health Service Act, as amended. The Board is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2): http://64.233.161.104/search?q=cache:BU0y_TPyJ-EJ:www1.od.nih.gov/cmo/committee/AdvisoryCmteUpdatedJuly3003.pdf+NLM+Board+of+Regents+FACA&hl=en#98.

validating the accuracy and interpretation of research results. NIH also recognizes that publication in peer-reviewed journals is a major factor in determining the professional standing of scientists; institutions use publication in peer-reviewed journals in making hiring, promotion, and tenure decisions. These important corollary benefits of peer review will not be affected by the Policy, as the Policy relies on the peer review system of journals; only peer-reviewed articles accepted for publication will be posted in PubMed Central.